REMARKS

Status of the Claims

Claims 1-30 and 32-37 were rejected. Claims 1-4, 8-14 and 16-37 have been canceled without prejudice or disclaimer. Applicants reserve the right to file a continuation or divisional application for the canceled subject matter. Claims 5, 6, 7, and 15 remain pending.

Claim 15 has been amended to recite treating or protecting against the "R6x" or "Type 4" pneumococcal infection. Support for this amendment can be found, for example, on page 70, lines 26-29 of the specification. Claims 5 and 7 have been amended to change dependency. No new matter has been added by way of these amendments.

The Rejection of the Claims for Obviousness-type Double Patenting Should Be Withdrawn

Claims 1-30 and 32-37 were rejected for obviousness-type double patenting in view of claims 9, 11-13, 20, 24, 25 and 48 of U.S. Patent No. 6,858,706. This rejection is respectfully traversed.

The instant application is a divisional application of U.S. Patent No. 6,858,706. The Examiner's attention is draw to the Office Action mailed August 21, 2002 for U.S. Patent No. 6,858,706 which contained a supplemental Restriction Requirement. Specifically, the Examiner states in the 8/21/02 Action that "polypeptide vaccine claims properly correspond to group V, claims 42-43, in the original restriction requirement (Paper No. 10)." In light of this restriction under 35 U.S.C. §121, all vaccine claims entered in the application corresponding to U.S. Patent No. 6,858,706 were canceled. Double patent rejections are prohibited when the claims in the divisional application were necessitated by a restriction under 35 U.S.C. §121. As such, the Examiner is respectfully requested to withdraw the rejection for obviousness-type double patenting.

The Rejection Under 35 U.S.C. § 112, First Paragraph, Should be Withdrawn

The Examiner rejected claims 1-30 and 32-37 under 35 U.S.C. § 112, first paragraph, on the grounds that the specification does not provide an enabling disclosure for these claims. This

rejection is respectfully traversed. Claims 1-4, 8-14 and 16-37 have been canceled. Claim 15 has been amended.

1. The Examiner states that the specification does not provide sufficient guidance for the enablement of a vaccine for treating or protecting against any and all pneumococcal infections comprising a polypeptide in a pharmaceutically acceptable carrier, wherein said polypeptide comprises a variant of SEQ ID NO:4. While Applicant's, for the reasons previously made of record, continue to disagree with this conclusion, to expedite prosecution claim 15 has been amended to recite that the vaccine protects against the R6x pneumococci and type 4 pneumococci. The specification teaches that polypeptides from the type 4 pneumococci serotype provide a cross-protective effect against the R6x strain. As such, amended claim 15, 5, 6 and 7 are enabled under 35 U.S.C. §112, first paragraph, and the rejection of the claims should be withdrawn.

2. The Examiner states that the specification is not enabled for variants of at least "one to 15 amino acid substitutions." As stated in the response filed on 1/17/07, Applicants maintain that the specification is enabled for the recited variants. In an effort to expedite prosecution, however, the claims have been amended to recite a vaccine comprising SEQ ID NO:4. As amended, the objection to the claims has been obviated, and the rejection should be withdrawn.

3. Newly amended claim 15 recites a vaccine comprising SEQ ID NO:4. The response filed on 1/17/07 provides extensive sequence analysis which demonstrates one of skill in the art would predict SEQ ID NO:4 to confer a protective effect on the R6x serotype. The Examiner appears to accept these arguments, however, the Examiner raises a new question in the most recent Action. Specifically, the Examiner states "It is noted that SEQ ID NO:4 is only a quarter of the size of SEQ ID NO:3, is there evidence that indicates that the portion of SEQ ID NO:3 that is similar to SEQ ID NO:4 is the portion of the polypeptide that contains the epitopes and/or confers protection against pneumococcal infection? Has the structure/function correlation of these two polypeptides been established?" (Page 10, lines 2-8 of 4/17/07 Office Action). A

structural/functional analysis of SEQ ID NO:4 and SEQ ID NO:3 does indeed allow one to conclude that it is Domain A in SEQ ID NO:3 (which shares 96% similarity to SEQ ID NO:4) that is conferring the cross-protective effect to serotype R6x.

SEQ ID NO:3 is longer than SEQ ID NO:4. SEQ ID NO:3 comprises the following 3 regions: 1) an N-terminal region; 2) Domain A; and 3) Domain B. (See, Appendix 1 filed with response of 1/17/07.) SEQ ID NO:4 comprises Domain C which shares 96% similarity to Domain A. The additional sequences found in SEQ ID NO:3 on the N-terminal side share only 29% sequence identity to the corresponding region of the CbpA protein from serotype R6x. The additional sequences found in SEQ ID NO:3 on the C-terminal side (Domain B) share only 6% sequence identity to the corresponding region of the CbpA protein from serotype 6. Given that SEQ ID NO:3 (derived from serotype 4) was shown to provide a protective effect against serotype R6x, such an effect would occur via *conserved epitopes* shared between the CbpA proteins from both serotypes. Domain A in SEQ ID NO:3 shares 96% similarity to SEQ ID NO:4 and thus contains a significant degree of structural similarity, when compared to the additional 2 domains contained in SEQ ID NO:3 (i.e., 29% identity and 6% identity). Thus, in light of the structural and functional studies performed, one of skill in the art would accept that SEQ ID NO:4 would provide a protective effect against both the R6x serotype and the Type 4 serotype as recited in the instant claims.

Thus, in view of the data in the specification, the structural relationship between SEQ ID NO: 3 and 4, and the state of art, claims 5, 6, 7 and 15 are enabled.

## CONCLUSION

It is submitted that this application is ready for allowance. In view of the above amendments and remarks, the Examiner is respectfully requested to withdraw the rejections and allow claims 5, 6, 7, and 15.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required

therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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**ELECTRONICALLY FILED USING THE EFS-WEB ELECTRONIC FILING SYSTEM OF THE UNITED STATES PATENT & TRADEMARK OFFICE ON OCTOBER 12, 2007.**